510(k) Summary

JUL 0 2 2013

Date:	20 June 2013
Sponsor:	SIGNUS Medizintechnik GmbH Industriestrasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-136 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Joachim Schneider, Quality Management/Regulatory Affairs
Trade Names:	MOBIS® II
Device Classification	Class II
Classification Name:	Intervertebral fusion device with bone graft, lumbar
Regulation:	888.3080
Device Product Code:	MAX
Device Description:	The basic shape of the MOBIS® II devices is a hollow structural frame having a rounded, tapered leading face. The upper and lower aspects of the implant are open. Surface spikes assist in the positive anchorage and seating of the implant between the vertebral bodies. The device is available in a variety of sizes and two angulations thereby enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.
Intended Use:	When used as an intervertebral fusion device, the MOBIS® II devices are intended for use at one or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous nonfusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.
Materials:	The MOBIS® II devices are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio®) as described by ASTM F2026. Integral marker pins used in the devices are manufactured from tantalum as described by ASTM F560.
Predicate Devices:	MOBIS® and PEEK TETRIS™ (K111792) Python (K090064)
Performance Data:	Mechanical testing of the worst case MOBIS® II was performed according to ASTM F2077 and included static and dynamic compression. The subsidence properties were evaluated according to ASTM F2267. The mechanical test results demonstrate that the MOBIS® II device performance is substantially equivalent to the predicate devices.

Technological Characteristics:

MOBIS® II possesses the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (hollow structural frame),
- material (PEEK polymer and tantalum), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate).

Therefore the fundamental scientific technology of the MOBIS® II device is the same as previously cleared devices.

Conclusion:

The MOBIS® II devices possess the same intended use and technological characteristics as the predicate devices. Therefore the MOBIS® II is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2013

SIGNUS Medizintechnik GmbH
% BackRoads Consulting, Incorporated
Dr. Karen E. Warden
Representative / Consultant
P.O. Box 566
Chesterland, Ohio 44026

Re: K131372
Trade/Device Name: MOBIS® II
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 8, 2013
Received: May 13, 2013

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For 

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 - Indications for Use Statement

510(k) Number: K131372

Device Name: **MOBIS® II**

Indications for Use:

When used as an intervertebral fusion device, the MOBIS® II devices are intended for use at one or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment. Patients with previous nonfusion spinal surgery at the involved level may be treated with the device. The devices are intended for use with a supplemental internal fixation system and with autograft to facilitate fusion.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices